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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,975	03/16/2004	Robert S. Biscup	MEDR 2 00001	2554
27885	7590	03/19/2008		
FAY SHARPE LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 03/19/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/801,975

Applicant(s)

BISCUP ET AL.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53, 77-80 and 82 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 13, 38, 40-52, 77, 79 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 14-37, 39, 53, 78 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/28/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election of species 9 (Figure 13) and subspecies b (hardening by chemical reaction) is noted. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §818.03(a)).

Based on the above election, the Examiner is withdrawing claims 9-11, 13, 38, 40-52, 77, 79 and 82 since they are directed to non-elected species. Accordingly, claims 1-8, 12, 14-37, 39, 53, 78 and 80 have been examined on the merits in this office action.

### ***Oath/Declaration***

The oath or declaration is defective since it does not have the correct statement with respect to the duty to disclose, namely, "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56" It is suggested that Applicants use the standard PTO/SB/01 form.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

At least claims 1-4, 7, 21, and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 16 and 36 of U.S. Patent No. 6,478,822.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims of the present application and patented claims is that the patented claims are more specific. Thus the invention of the patented claims is in effect a "species" of the "generic" invention of the claims of the present application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims of the present application are anticipated by the patented claims, they are not patentably distinct from the patented claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12, 15-22, 24-33, 35-37, 39, 53, 78 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (US 5,571,189).

Kuslich discloses a prosthetic implant including: a substantially spherical bag 40 made of a material impregnated with a biologically active material such as ground up bone graft; and an inflatable band or "expandable component" or "stabilizer" 42 having a disc shape (Figs. 9 and 13, col. 6, lines 57-67, cols. 7-9 and col. 10, lines 1-9).

Kuslich also discloses the use of hydroxyapatite to fill the implant (col. 12, lines 16-22). It is noted that materials such as hydroxyapatite expand as they harden.

The method steps of claims 78 and 80 are inherently performed when the Kuslich implant is filled with hydroxyapatite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (US 5,571,189).

Regarding claim 14, although Kuslich does not disclose the relative dimensions of the band with respect to the balloon, it has been held that, where the only difference between the prior art and the claims is the recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than a prior art device, the claimed device is not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F. 2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding claim 23, although Kuslich does not specifically disclose the expandable component to have a tapered edge, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the Kuslich band with a shape having a tapered edge, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a stabilizer element. In re Dailey and Eilers, 149 USPQ 47 (1966).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
March 17, 2008

/Anu Ramana/  
Primary Examiner, Art Unit 3733